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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,568	11/07/2001	Tracy Willson	11373Z	4029

7590 06/03/2005

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EXAMINER	
BASI, NIRMAL SINGH	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/036,568	WILLSON ET AL.	
	Examiner	Art Unit	
	Nirmal S. Basi	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 November 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/7/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.S.O.

DETAILED ACTION

1. Amendments filed 7/11/03 has been entered in part. The paragraph beginning on page 31, line 10 has not been entered because some of the requested amendments do not exist in the specification. Applicant has cancelled "BRIEF DESCRIPTION OF THE FIGURES" to be replaced with "BRIEF DESCRIPTION OF THE DRAWINGS". The amendment filed 11/7/01 amended the language on page 31, line 11 to read "BRIEF DESCRIPTION OF THE DRAWINGS". Therefore the phrase "BRIEF DESCRIPTION OF THE FIGURES" is not present in the specification on page 31, line 10. Also the amendment filed 7/11/03 states typographical errors in the sequence listing of SEQ ID NOs:1 and 2 have been corrected and indicated support for the correction is found in Figure 1 or in the priority documents. Applicant must disclose the specific changes made so that the Examiner can determine if new matter has been introduced. At present it is not clear which part of the sequence is changed and where the changes find specific support.

In the Amendment filed 11/7/05 Applicant has cancelled claims 1-35 and added new claims 36-51 pertaining to the polypeptide of SEQ ID NO:4. Claims 36-51 will be examined.

Specification

2. Acknowledgment is made of applicant's claim for foreign priority based on application filed in Australia on 10/23/95, 12/22/95 and 9/9/96 numbered PN-

6135, PN-7276 and PO-2208 respectively. It is noted, however, that applicant has not filed a certified copy of applications PN-6135, PN-7276 and PO-2208 as required by 35 U.S.C. 119(b).

3. The disclosure is objected to because of the following informalities:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78) as well as the relationship of instant application to the parent.

The amendment filed 11/7/01 has been entered but has introduced an incorrect filing date (10/23/96) for the priority document 09/051,843. The Application was filed 6/29/1998. Appropriate correction is required.

4. The drawings objected to because each Figure must be described separately in the Brief Description of the Drawings. The labeling of the Figures does not match their description in the specification. For example: a) Figure 1 is labeled as Fig. 1, Fig. 1(i), Fig. 1(ii), Fig. 1(iii), Fig. 1(iv), Fig. 1(v) and Fig. 1(vi) but described in the Brief Description of the Drawings as Figure 1A-1F. Figure 3 contains 3 figures (A-C) but described in the Brief Description of the Drawings state Figures 3A-3B. Figure 4 contains 2 figures (A-B) but described in the Brief Description of the Drawings state Figures 4A-D. Figure 5 contains 1 figures (A) but described in the Brief Description of the Drawings state Figures 5A-B. Figure 7 is labeled as Fig. 7, Fig. 7(i), Fig. 7(ii), Fig. 7(iii), Fig. 7(iv), Fig. 7(v), Fig. 7(vi),

Fig. 7(vii), Fig. 7(viii), Fig. 7(ix) and Fig. 7(x) but described in the Brief Description of the Drawings as Figure 7A-7J. Figures must described separately in the Brief Description of the Drawings as required by 37 C.F.R. § 1.84 (u)(1). Appropriate correction is required. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because of the numbering problem disclosed above. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

5. ***Sequence Rules Compliance***

This application fails to comply with the sequence rules, 37 CFR 1.821-1.825. Nucleotide and polypeptide sequences must be identified with the corresponding SEQ ID NO. Title 37, Code of Federal Regulations, Section 1.821 states "reference must be made to the sequence by use of the assigned identifier", the identifier being SEQ ID NO. Sequence in Figure (FIG.6) must be identified by the corresponding SEQ ID NO:. Also application fails to comply with the Sequence Rules, 37 CFR 1.821 et seq., because amino acid sequence on page 37 is not identified by SEQ ID NO. Compliance with sequence rules is required.

Claim Rejection, 35 U.S.C. 112, second paragraph

6. Claims 36-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 is indefinite because it not clear what is a "derivative of SEQ ID NO:4". "Derivative" has not been defined in the claims or specification so as to allow the metes and bounds of the claim to be determined. Further the claim is indefinite because the term "derivative" carries no weight in terms of structure and function and encompasses numerous alterations and reads on unrelated polypeptide molecules.

Claim 36 s indefinite because the claim does not define the structure of the polypeptide that renders it capable of binding human Il-13 and/or human IL-4 therefore the metes and bounds of the polypeptides that meet the claim limitations cannot be determined. The functional limitation provides no structure for the claimed invention. It is suggested to overcome the rejection the polypeptide be identified by SEQ ID NO:.

Claim 41 is indefinite because it is not clear which isolated polypeptide is considered the soluble form so as to allow the metes and bounds of the claim to be determined. It is not clear which fragments of the polypeptide are considered soluble. Also soluble in what?

Claim 44 is indefinite because it is not clear what form of the polypeptide is considered the recombinant form and how it differs from the polypeptides of claims 36-40 so as to allow the metes and bounds of the claim to be determined.

Claim 45 is indefinite because it is not clear which isolated polypeptide is considered the mature form so as to allow the metes and bounds of the claim to be determined. It is not clear which fragments of the polypeptide are considered mature as compared to not mature. What is the minimum sequence that needs to present for the claimed polypeptide for it to be considered mature? The term mature is ambiguous as it relates to the protein because it is also not clear if mature is a functional term relating to activity or a structural term relating to the length of the polypeptide. Does mature refer to a state of glycosylation?.

Claim 46-50 are indefinite because it is not clear what the composition comprises. The composition is the product of combining or mixing of at least two elements or ingredients. In instant case the polypeptide is the one ingredient. It is not clear what is the second ingredient so as to allow the metes and bounds of the claim to be determined.

Claim 51 is indefinite because it is not clear what is considered a carrier so as to allow the metes and bounds of the claim to be determined. What does the carrier carry? What compounds are considered carriers as compared to not being carriers.

Claims 37, 42 and 43 are rejected for depending upon an indefinite base (or intermediate) claim and fails to resolve the issues raised above.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 36, 38-46, 48-51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolated polypeptide of SEQ ID NO:4, does not reasonably provide enablement for other polypeptides . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

While the person of ordinary skill in the art would, in light of the specification be able to isolate the polypeptide disclosed in SEQ ID NO:4 the scope of the claims, which encompass derivatives of undefined structure and function, and other polypeptides defined by only functional properties is not enabled by the disclosure. The disclosure does not teach how to make such functional derivatives or other polypeptides encompassed by the claims.

Although derivatives of IL-13 receptor can be made, said derivatives carry no weight in terms of structure and function and encompasses numerous alterations and reads on unrelated polypeptides. Also polypeptides defined only by functional properties carry no weight in terms of structure and function and encompasses numerous alterations and reads on unrelated polypeptides. For example any antibody that can cross react with IL-13 or Il-4 reads on the claim. The antibody does not even have to be specific for the Il-13 of SEQ ID NO:4. Other molecules structurally completely unrelated to the polypeptide of SEQ ID NO:4, but capable of binding IL-13 or IL-4 are encompassed by the claim.

Instant specification does not teach which particular amino acids are critical for the functionality of the Il-13 or Il-4 binding, i.e. the critical feature of the invention as it relates to function is not disclosed. Therefore structurally deficient polypeptides containing random mutations would be expected by the skilled artisan to result in molecules encoding inactive or unrelated proteins or polypeptides. For example, Rudinger states on page 3 that "it is impossible to attach a unique significance to any residue in a sequence. A given amino acid will not by any means have the same significance in different peptide sequences, or even in different positions of the same sequence". Rudinger further states on page 6 that "the significance of particular amino acid sequences for different aspects of biological activity cannot be predicted *a priori* but must be determined from case to case by painstaking experimental study". Therefore, the lack of guidance provided in the specification as to what minimal structural requirements are necessary for functional protein would prevent the skilled artisan from determining whether any modification or mutation of SEQ ID NO:4 or other protein encompassed by the claims could be made which retains the desired function of the instant invention, because any random mutation or modification manifested within said protein itself would be predicted to adversely alter its biologically active 3-dimensional conformation, without undue experimentation to determine otherwise.

The fact remains that polypeptides with a particular activity encompassed by the claims or the actual structure of the polypeptide cannot be envisioned any better when the possible choices are narrowed from all possible molecules to all

possible molecules that bind Il-13 and/or IL-4inhibit or those that are derivatives of SEQ ID NO:4 with no specific activity. For example, if one skilled in the art were to make a polypeptide with 90% identity to the reference amino acid sequence SEQ ID NO:4, he would be no more able to say whether it inhibits IL-4 binding if the polypeptide was only 10% identical to the reference polypeptide sequence. Nor would he be able to say whether the sequence existed in nature. The specification does not provide any information on what polypeptides apart from those disclosed above are necessary and sufficient for a functional activity. The specification also provides no teachings on what amino acid sequence modifications, e.g. insertions, deletions and substitutions, would be permissible in an active Il-13 receptor polypeptide that would improve or at least would not interfere with the biological activity or structural features necessary for the biological activity and stability of the protein. Therefore one cannot predict Il-13 receptor molecules required or a biologically activity. Rather one must engage in case-to-case painstaking experimental study to determine active variants. Consequently, excessive trial and error experimentation would have been required to identify the necessary variants since the structure of said variants could not be predicted.

8. Claims 36, 38-45 and 48-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

inventors, at the time the application was filed, had possession of the claimed invention. Claims are drawn to polypeptide, which is capable of binding human 1L-13 and/or human IL-4, and derivatives of the polypeptide disclosed in SEQ ID NO:4. The claims either provide a) functional limitation and no structural limitations or b) meaningless structural limitation (derivative) and no functional limitations. The phrase "polypeptide which is capable of binding human IL-13 and/or human IL-4 does not sufficiently describe the structure of the polypeptidess covered by the name. The phrase "derivative of SEQ ID NO:4" does not sufficiently describe the structure or function of the polypeptidess covered by the name. Every protein known to man is essentially a derivative of the polypeptide SEQ ID NO:4 since they share at least one common amino acid. The polypeptides encompassed by the claims have no disclosure of the critical technical feature of the claimed invention or its relationship to function. The critical technical feature encompassed by the polypeptide and how it relates structurally and functionally to the polypeptides of SEQ ID NO:4 is not disclosed. Thus, the claims are drawn to a genus of molecules that vastly varies in structure and function. It would take undue experimentation to discover the polypeptides encompassed by the claim. The specification does not provide any information on what polypeptides apart from SEQ ID NO:4 are necessary and sufficient for a functional activity. The specification also provides no teachings on what amino acid sequence modifications, e.g. insertions, deletions and substitutions, would be permissible in an active IL-13 receptor polypeptide that would improve or at least would not interfere with the biological activity or structural features

necessary for the biological activity and stability of the protein. Therefore one cannot predict the molecules required or a biologically activity. Rather one must engage in case-to-case painstaking experimental study to determine active variants. Consequently, excessive trial and error experimentation would have been required to identify the necessary polypeptide derivatives/variants since the structure of said derivatives/variants could not be predicted.

To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. Apart from the polypeptides of SEQ ID NO:4 there is no disclosure of a particular portion of the structure of other molecules that must be conserved and have the functionality of the claimed genus. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. When one is unable to envision the detailed constitution of a complex chemical compound having a particular function, such as a polypeptide, so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the polypeptide has been isolated. Thus, claiming all polypepties that

achieve a result without defining what means will do so is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived. The claims do not recite a structural relationship between the Il-13 receptor in terms of its structure and related specific function.

The fact remains that polypeptides with a particular activity or the actual structure of the Il-13 polypeptide cannot be envisioned any better when the possible choices are narrowed from all possible molecules to all possible molecules that for example are derivatives of the polypeptide of SEQ ID NO:4. For example, if one skilled in the art were to make a polypeptide with 90% identity to the reference amino acid sequence SEQ ID NO:4, he would be no more able to say whether it inhibits an undefined cellular receptor activity than if the polypeptide was only 10% identical to the reference polypeptide sequence. Nor would he be able to say whether the sequence existed in nature. In instant case the term "derivative" encompasses billion of compounds.

The specification does not provide any information on what polypeptides apart from those the polypeptide of SEQ ID No:4 are necessary and sufficient for a functional activity. The specification also provides no teachings on what amino acid sequence modifications, e.g. insertions, deletions and substitutions, would be permissible in an active IL-13 receptor polypeptide that would improve or at least would not interfere with the biological activity or structural features necessary for the biological activity and stability of the protein. Therefore one cannot predict which mutation would result in active Il-13 receptor molecules required for a particular biologically activity. Rather one must engage in case-to-

case painstaking experimental study to determine active derivatives/variants. Consequently, excessive trial and error experimentation would have been required to identify the necessary derivatives/variants since the structure of said derivatives/variants could not be predicted.

The specification discloses only one putative amino acid sequences, SEQ ID NO:4 for a polypeptide having the necessary properties of binding IL-13 and/or IL-4 and provides no guidance on obtaining other functional molecules, which would be suitable.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 , clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that (he or she) invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of IL-13 receptor polypeptide, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.,* 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird,* 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF'S were found to be unpatentable due to lack of written description for that broad class.

Therefore, only the use the isolated polypeptide disclosed by SEQ ID NO:4 but not the full breadth of the claims meets the written description provision of 35 U.S.C.j112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1 115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 36, 38, 41, 42, 45-48 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Abrams et al (US PATENT 5,041,381, 8/20/91).

Abrams discloses an antibody that binds IL-4 (see claim 1). Abrams also discloses an antibody that binds IL-4 and is present in a composition form (combined in PBS buffer). Since the antibody was contained in PBS buffer it is considered to be in the soluble form. Further since the antibody binds Il-4 it is considered mature. Also, since the antibody inherently has at least one amino

acid in common with the polypeptide of SEQ ID NO:4 it is considered a derivative of said polypeptide. Therefore the disclosure of Abrams meets the limitations of claims 36, 38, 41, 42, 45-48 and 51 by disclosing an isolated polypeptide which is capable of binding IL-4, is a derivative of the polypeptide of SEQ ID NO:4, is contained in a composition comprising a carrier, is mature and in soluble form, absent evidence to the contrary.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa can be reached on 571272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nirmal S. Basi
Art Unit 1646
May 27, 2005

JOSEPH MURPHY
PATENT EXAMINER